

OLYMPUS

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510(k) SUMMARY VIDEOSCOPE XCHF-T160

OCT 21 2008

1. General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
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Establishment Registration No: 8010047
- Official Correspondent: Stacy Abbatiello Kluesner, RAC
Regulatory Affairs & Quality Assurance
Olympus America Inc.
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Center Valley, PA 18034-0610
Phone: (484) 896-5405
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Email: Stacy.Kluesner@olympus.com
Establishment Registration No: 2429304
- Manufacturer: Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-Niidera, Monden-machi,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No.: 9610595
- Date Prepared: August 21, 2008

2. Device Identification

- Device Name: XCHF-T160 Videoscope
- Common Name: Videoscope
- Class: II
- Regulation Number/Name: 876.1500 Endoscope and accessories
- Product Code: FBN
- Classification Panel: Choledochoscope And Accessories, Flexible

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3. Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the subject device and the predicate device to which we claim substantial equivalence.

Table 14-1. Primary Component & Predicate Device

Subject Device (Part of this submission)	Predicate Device	PD's 510(k) No.
VIDEOSCOPE XCHF-T160	CHOLEDOCHOSCOPE CHF-B20	K904799
	EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z	K011151

4. Device Description

The XCHF-T160, is a flexible video endoscope used for endoscopy and endoscopic surgery within the biliary tract. The XCHF-T160 is basically identical to the predicate device, Olympus CHF-B20 Choledochoscope, hereinafter referred to as CHF-B20 in intended use, specifications, performance.

The optical system of the XCHF-T160 is a charge coupled device (CCD) based system, allowing endoscopic image display on a video monitor.

The new endoscope is basically identical to each predicate device shown in Table 14-1 in intended use, and similar in specifications, performance and materials.

5. Indications for Use

VIDEOSCOPE XCHF-T160

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within the biliary tract.

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6. Comparison of Technological Characteristics

The XCHF-T160 is similar to the predicate device CHF-B20 in specifications except for the material and optical system. Comparison between the subject and predicate devices is shown below.

Table 14-2. Comparison of Specifications

Specifications	Subject Device XCHF-T160	Predicate Device 1 CHF-B20	Predicate Device 2 GIF-Q160Z
Field of View	90°	100°	140°
Depth of Field	1-50mm	3-50mm	WIDE : 8-100mm TELE : 1.5-3mm
Direction of View	Forward	Forward	Forward
Type of CCD Chip	Inter color CCD (37071)	—	Inter color CCD (3704)
Outer Diameter of Distal End	φ 5.7mm	φ 4.1mm	φ 10.8mm
Outer Diameter of Insertion Tube	φ 5.5mm	φ 4.5mm	φ 10.9mm
Angulation UP/DOWN	U 160° D 100° R 100° L 100°	U 160° D 100°	U 210° D 90° R 100° L 100°
Working Length	1330mm	1870mm	1030mm
Inner Diameter of Instrument Channel	φ 2.0mm φ 1.2mm	φ 1.7mm	φ 2.8mm

7. Conclusion

When compared to the predicate device, the CHF-B20 does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2008

OLYMPUS MEDICAL SYSTEMS CORP.
c/o Stacy Abbatiello Kluesner, RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
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P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K082576
Trade/Device Name: VIDEOSCOPE XCHF-T160
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: II
Product Code: FBN
Dated: September 4, 2008
Received: September 9, 2008

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082576

Device Name: **VIDEOSCOPE XCHF-T160**

Indications For Use:

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories such as biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within the biliary tract.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal, and
Radiological Devices

510(k) Number K082576

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